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NOTICE OF ALLOWANCE AND FEE(S) DUE

26817 7590 06/17/2009

MATHEWS, SHEPHERD, MCKAY, & BRUNEAU, P.A.
29 THANET ROAD, SUITE 201
PRINCETON, NJ 08540

EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 06/17/2009

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/580,805

03/16/2007

Ronald Quinn

3573-117 US

8855

TITLE OF INVENTION: NOVEL ANALGESIC COMPOUNDS, EXTRACTS CONTAINING SAME AND METHODS OF PREPARATION

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1510 | \$300 | \$0 | \$1810 | 09/17/2009 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26817 7590 06/17/2009

MATHEWS, SHEPHERD, MCKAY, & BRUNEAU, P.A.
29 THANET ROAD, SUITE 201
PRINCETON, NJ 08540

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

| |
|--------------------|
| (Depositor's name) |
| (Signature) |
| (Date) |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/580,805 03/16/2007 Ronald Quinn 3573-117 US 8855

TITLE OF INVENTION: NOVEL ANALGESIC COMPOUNDS, EXTRACTS CONTAINING SAME AND METHODS OF PREPARATION

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|-------------|--------------|---------------|---------------------|----------------------|------------------|----------|
|-------------|--------------|---------------|---------------------|----------------------|------------------|----------|

nonprovisional NO \$1510 \$300 \$0 \$1810 09/17/2009

| EXAMINER | ART UNIT | CLASS-SUBCLASS |
|----------|----------|----------------|
|----------|----------|----------------|

OLSON, ERIC 1623 514-033000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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| 10/580,805 | 03/16/2007 | Ronald Quinn | 3573-117 US | 8855 |
| 26817 | 7590 | 06/17/2009 | EXAMINER | |
| MATHEWS, SHEPHERD, MCKAY, & BRUNEAU, P.A. 29 THANET ROAD, SUITE 201 PRINCETON, NJ 08540 | | | OLSON, ERIC | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |
| DATE MAILED: 06/17/2009 | | | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 120 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 120 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

| | | | |
|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 10/580,805 | QUINN ET AL. | |
| | Examiner | Art Unit | |
| | ERIC S. OLSON | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment submitted December 31, 2008.
2. ☒ The allowed claim(s) is/are 1-5 and 7-26.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____. 7. <input type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|--|--|

/Eric S Olson/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

Detailed Action

This office action is a response to applicant's communication submitted December 31, 2008 wherein claims 1, 3, 4, 24, and 26 are amended and claim 6 is cancelled. This application is a national stage application of PCT/AU04/01660, filed November 26, 2004, which claims priority to foreign application AU2003906558, filed November 27, 2003.

Claims 1-5 and 7-26 are pending in this application.

Claims 1-5 and 7-26 as amended are examined on the merits herein.

Reasons for Allowance

Applicant's amendment, submitted December 31, 2008, with respect to the objection to claim 1 for reciting the probable typographic error "CH₂OO-alkyl", has been fully considered and found to be persuasive to remove the objection as the claim has been amended to recite the structure "CH₂COO-alkyl," which is in line with the structures recited in the specification. Therefore the objection is withdrawn.

Applicant's amendment, submitted December 31, 2008, with respect to the rejection of claims 4 and 6 under 35 USC 112, second paragraph for indefinitely reciting limitations with no antecedent basis in the base claim 1, has been fully considered and found to be persuasive to remove the objection as claim 4 has been amended to remove the species which lack antecedent basis and claim 6 has been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted December 31, 2008, with respect to the rejection of claim 26 under 35 USC 112, first paragraph for lacking enablement for a method of treating neuropathic or psychogenic pain, has been fully considered and found to be persuasive to remove the objection as claim 26 has been amended to recite only nociceptive pain. Therefore the rejection is withdrawn.

Currently claims 1-5 and 7-26 are pending in this application and have been examined on the merits herein. Applicant's amendment submitted December 31, 2008, is seen to be persuasive to remove all rejections of record in the previous office action and place the application in condition for allowance. Reasons for allowance are as follows:

The claimed compounds and methods are seen to be adequately described and enabled by the specification as originally filed. For example pp. 7-9 of the specification disclose the chemical structure recited in claim 1. Pp. 9-10 disclose various specific chemical structures including those recited in claims 7-23. Pp. 23-28 discloses methods enabling one skilled in the art to obtain the compound from the bark of *Barringtonia acutangula*. Figures 65-69 in the drawings disclose antinociceptive and antiinflammatory activities of the claimed compounds, and the experimental methods on pp. 16-20 and 45-48 disclose analgesic activity for these compounds that enables one skilled in the art to use them for treating nociceptive pain. Therefore the claimed invention meets the requirements of 35 USC 112.

Furthermore the claimed invention is novel and non-obvious over the prior art. The compounds claimed in claim 1 are not known or fairly suggested by the prior art. Specifically, although certain prior art reference such as Chan et al. (US patent 7262285, cited in PTO-892) Pal et al., Crublet et al., Wang et al., Burczyk et al., and Kitagawa et al. (References of record in PTO-1449 submitted March 17, 2008) disclose similar structures to instant claim 1, these structures do not actually anticipate the claims. Specifically, Chan et al. does not have support under 35 USC 102(e) for any compound of the claimed structure before the effective filing date of the instant claims, November 27, 2003. The only priority document for this patent that would antedate the effective filing date of the instant claims is provisional application 60/509851, which does not provide any support for the claimed structures. Therefore Chan et al. is not a reference under 35 USC 102(e). Kitagawa et al. discloses saponin glycosides, but these glycosides have a glucose residue in the saccharide moiety as opposed to the galactose in the instantly claimed compounds. Burczyk et al. discloses saponin trisaccharides having a similar structure, but with an arabinopyranosyl saccharide in place of the xylopyranosyl residue of the instant claims. Pal et al. discloses similar compounds wherein R_4 is $\text{CH}_2\text{O}(\text{C}=\text{O})$ -isopropyl, which is not included in the definition of R_4 in the instant claims, and structures wherein R_4 is CH_2OH and R_2 and R_3 are both hydroxyl, which are specifically excluded from the structures of instant claim 1. Wang et al. discloses similar compounds wherein R_4 is CH_2O -tigloyl, which is not included in the definition of R_4 in the instant claims, and structures wherein R_4 is CH_2OH and R_2 and R_3 are both hydroxyl, or R_2 is alkenoyl and R_3 is hydroxyl, which are specifically excluded

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from the structures of instant claim 1. Crublet et al. discloses similar compounds wherein R_4 is $\text{CH}_2\text{O}(\text{C}=\text{O})$ -isobutyl, which is not included in the definition of R_4 in the instant claims, and structures wherein R_4 is CH_2OH and R_2 and R_3 are both hydroxyl, or R_3 is O-alkanoyl and R_2 is O-acetyl, which are specifically excluded from the structures of instant claim 1. Therefore none of these references teach compounds having structures that anticipate the instant claims. Because none of the references describe any actual uses for the disclosed natural products, there would be no motivation for one of ordinary skill in the art to modify or optimize these compounds to arrive at the claimed structures. Therefore the invention meets the requirements of 35 USC 102 and 103.

Accordingly, Applicant's amendment submitted December 31, 2008, is sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/

Examiner, Art Unit 1623

6/5/2009

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623